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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/494,149	01/28/2000	Spencer R. Malecha	A-67641-1/RFT/DSS	3091

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EXAMINER

PARAS JR, PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/06/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/494,149

Applicant(s)

MALECHA ET AL.

Examiner

Peter Paras

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12. 6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 1/14/02 has been entered.

Upon entry of the request for continued examination claims 1-11 are pending and are under current consideration.

Drawings

New formal drawings are required in this application because of the objections to the drawing by the draftsman as set forth in the PTO 948 mailed on 7/27/00. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37CFR

1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. Any response to this Office Action, which fails to meet all of these requirements, will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

To avoid damage to a CRF by irradiation, a reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
(<http://www.uspto.gov/ebc/efs/downloads/documents.htm>), EFS Submission User Manual - ePAVE)
2. Mailed to: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. Mailed by Federal Express, United Parcel Service or other delivery service to: U. S. Patent and Trademark Office, 2011 South Clark Place, Customer Window, Box Sequence, Crystal Plaza Two, Lobby, Room 1B03, Arlington, Virginia 22202
4. Hand Carried directly to the Customer Window at: 2011 South Clark Place, Crystal Plaza Two, Lobby, Room 1B03, Box Sequence, Arlington, Virginia 22202

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-11 as originally filed are rejected under U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The previous rejection is maintained for the reasons of record advanced on page 3 of the Office action mailed on 4/11/01.

The claims are directed to a population of genetically and phenotypically normal shrimp or prawns, having a skewed percentage of females to males, in particular the percentage of females is greater than 90%. As such the claims read on a product of nature, which is non-statutory subject matter. Claim 10 is a product by process claim in which the process carries little patentable weight because the product does not recite distinguishing features as a result of carrying out the claimed method. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). The claims are interpreted as being directed to a population of normal shrimp or prawns.

Applicant's arguments filed on September 19, 2001 have been fully considered but are not persuasive. Applicants have argued that shrimp or prawns do not naturally produce a skewed population of females to males. Applicants have also argued that the claims are not directed to the individual shrimp, but rather to a population of shrimp and further argue that a population having a skewed percentage of females to males of greater than 80-100% is statutory subject matter. In light of the preceding arguments Applicants assert that skewed populations as claimed do not exist in nature. Applicants also assert

that statistical analysis in the area of breeding ratios can actually define how skewed the population of the claimed invention differs from a wild-type population. See the amendment on pages 3-4.

In response, the Examiner maintains that the claims read on a normal population of shrimp or prawns; the shrimp or prawns as claimed are genetically and phenotypically normal. It is further maintained that the process of breeding a neomale shrimp with a normal female does not make the progeny different from other wild-type shrimp or prawns. A population can be interpreted to be 1 or more shrimp or prawns. When considering such an interpretation 2 female shrimp together without a male would be a population of shrimp having a skewed percentage of females to males, wherein the percentage is 100%. Furthermore, the claims as written would certainly encompass shrimp or prawns that have been collected and sexed such that the males and females are separated into different holding areas to comprise populations of female and male shrimp respectively. In light of the above considerations a population of shrimp having a skewed percentage of females to males of greater than 80-100% is still considered to be non-statutory subject matter contrary to Applicant's assertions. Also, see Malecha and Nakashima under 102 rejections as evidence of the above considerations.

Accordingly, the rejection is maintained for the reasons of record and as discussed in the preceding paragraph.

The following are new grounds of rejection under 35 U.S.C. 112, first paragraph:

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-5 as amended or originally filed are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a composition comprising an isolated shrimp or prawn androgenic polypeptide that is capable of producing a sexually reproductive neomale shrimp or prawn. The claims are further directed to using such a composition to produce sexually reproductive a neomale shrimp or prawn.

The amino acid sequences that encode all androgenic peptides encompassed within the genus of androgenic peptides, embraced by the instant claims, have not been disclosed. Based upon the prior art there is expected to be variation among the amino acid sequences of the species of androgenic peptides, because the sequences of cDNAs that encode androgenic peptides would be expected to vary among individuals. The specification discloses isolation of an androgenic peptide from a single species of prawn,

Macrobrachium rosenbergii, and from a single species of shrimp, the marine shrimp *Penaeus vannamei*, but the specification does not disclose the isolation of other androgenic peptides from other species of shrimp or prawn or from any other species of animal. [It is noted that although androgenic peptides have been isolated from *Macrobrachium rosenbergii* and *Penaeus vannamei* the specification has not provided the amino acid sequences of such. It is further noted that the specification is not required to provide any sequences.] There is no evidence on the record of a relationship between the structures of the various species of shrimp androgenic peptides or the various species of prawn androgenic peptides. Further, the evidence of record has not described a structural relationship between the androgenic peptides of Decapods (which include shrimp and prawns). Still further, the evidence of record has not provided a description of the structural relationship between the claimed androgenic polypeptides embraced by the claims, which include androgenic polypeptides of all animal species. Moreover, the evidence of record has failed to provide any reliable information about the structural relationship of androgenic peptides within the genus. Even more, the evidence of record has failed to describe the structural features that distinguish members of the genus of androgenic peptides from other proteins.

It would appear from the evidence of record that Applicants, at the time the claimed invention was filed, were not in possession of the common attributes that identify members of the genus of androgenic peptides. The claimed invention as a whole is not adequately described if the claims require essential or

critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date.

Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

Finally, the point can be made that no evidence has been provided of a known structural relationship between the asserted shrimp and prawn androgenic peptides, disclosed by the instant specification, to any other androgenic peptide sequences; the specification has not disclosed the sequence of any of the claimed androgenic peptides or provided any information as the degree of homology between of any of the claimed androgenic peptides or described any identifying structural attributes of androgenic peptides. As such the evidence of record has failed to provide a correlation between the structure of any androgenic peptide and its function. In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus of androgenic peptides, because an isolated shrimp or prawn androgenic peptide is not representative of the claimed genus. Therefore, Applicant was not in possession of the genus of androgenic peptides as encompassed by the claims as the attributes that identify the members of the genus have not been described. Adequate written description requires more than a mere statement that it is part of the invention

and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of claim 1 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the androgenic polypeptide recited in the claim is capable of producing a sexually reproductive neomale shrimp or prawn.

Applicant's arguments are moot as the rejection has been withdrawn.

The following are new grounds of rejection under 35 U.S.C. 112, second paragraph:

Claims 6-10 as originally filed are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 as written recites inconsistent language, such that the goal of the preamble is not set forth in the claim. For example, the preamble is directed to a method of producing a population of shrimp or prawns having a skewed

percentage of females to males, however the last phrase of the claim sets forth that a population of shrimp or prawns having a skewed ratio of males to females is produced. Appropriate correction is necessary so that the claim recites consistent language. Claims 7-10 depend from claim 6.

The following are new grounds of rejection under 35 U.S.C. 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, and 10-11 as amended or originally filed are rejected under 35 U.S.C. 102(b) as being anticipated by Malecha (Aquaculture, 1992, 105: 201-218; IDS-ref #2).

The claims are directed to a composition comprising an isolated shrimp or prawn androgenic polypeptide that is capable of producing a sexually reproductive neomale shrimp or prawn. The claims are further directed to using such a composition to produce sexually reproductive a neomale shrimp or prawn. The claims are further directed to populations of shrimp or prawns having a skewed percentage of females to males, in particular a percentage of 90% or greater females to males.

Malecha et al teach the isolation of androgenic glands from male prawns (*Macrobrachium rosenbergii*). See page 203 in the Materials and Methods section in the third paragraph. Malecha teaches that the dissected androgenic glands are placed in a saline solution and then implanted into juvenile female prawns. See page 203 in the Materials and Methods section in the third and fourth paragraphs. Some of the female prawns comprising the implanted androgenic gland developed into sexually reproductive neomales. See pages 204-205; the section entitled Breeding and sex-determination procedures, and Table 1 on page 206. Malecha has taught that the androgenic gland produces a hormone that is responsible for differentiation of primary and secondary male sexual characteristics. See page 202, in the second paragraph. The claim limitations directed to a composition comprising an isolated shrimp or prawn androgenic polypeptide are anticipated by an isolated androgenic gland in a solution as taught by Malecha (see above). Since it has been established that the androgenic gland produces a hormone responsible for male sex differentiation it would be inherent that when in solution the androgenic gland would secrete androgenic hormone to produce a composition comprising an isolated androgenic polypeptide. Finally, Malecha has taught that breeding neomale prawns with normal female prawns produces a population of progeny that is has a skewed percentage of females to males; in some cases Malecha reports that the percentage of females to males was greater than 90%. See page 211, Table 5, panel B, line 2, where it is reported that neomale 7 produced a sex-ratio of 1:22.18 (males to females), which is the equivalent of a population

that is greater than 90% females to males, when backcrossed to normal females. Also see lines 3-5 of page 211 where Malecha reports that certain broods comprised sex ratios of zero : 1,809 and 1 : 1,578, males to females, respectively. It is noted that claim 10 is a product by process claim that is interpreted to read on a normal population of prawns because the method of making the prawns produced a population of normal prawns, the method not adding any distinguishing characteristics to the prawns. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). Amending claims 1 and 3-5 to read on a composition consisting essentially of an androgenic peptide may be sufficient to overcome the rejection.

In addition, as claims 10-11 are interpreted to read on a normal shrimp or prawn population having a skewed percentage of females to males, particularly greater than 90% female, it is of importance for the record to state that Malecha et al also teach three separate populations female prawns [that are different from the populations obtained from breeding neomale prawns as discussed above], wherein the populations do not comprise any male prawns. See page 203, the Material and Methods section, in the second full paragraph.

Thus, the teachings of Malecha meet all of the instant claim limitations.

Claims 10-11 as originally filed are rejected under 35 U.S.C. 102(b) as being anticipated by Nakashima et al (J. Ethology, 1987, 5: 145-159).

The claims are directed to a population of shrimp or prawns having a skewed percentage of females to males, in particular the percentage of females is greater than 90%. Claim 10 is a product by process claim in which the process carries little patentable weight because the product does not recite distinguishing features as a result of carrying out the claimed method. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). The claims are interpreted as being directed to a population of normal shrimp or prawns.

Nakashima et al teach a single female clam shrimp kept alone and separate from male shrimp. See page 150, the first full paragraph and also see Table 1 on page 151. A single female shrimp kept alone in a holding container represents a population of 1 female shrimp for that container. Since there are no male shrimp present in the container the percentage of female to male shrimp is 100%.

Thus, the teachings of Nakashima meet all of the instant claim limitations.

Claim 2 as amended is rejected under 35 U.S.C. 102(b) as being anticipated by EP 0514015A1 (11/19/92; IDS received on 2/13/02).

The claim is directed to a sexually reproductive neomale shrimp or prawn, which does not contain transplanted androgenic gland tissue.

EP 0514015A1 teaches a shellfish that is genotypically female but phenotypically male. See page 3, the first sentence. Shellfish are defined by EP 0514015A1 to encompass any crustacean, including shrimp and prawns, which

can be cultivated under aquaculture conditions. See page 3, in lines 7-8. The instant specification has defined neomale as genotypic female shrimp or prawn that has been sex-reversed and exhibits a male phenotype. See page 5 of the specification.

Thus, EP 0514015A1 anticipates all the limitations of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The previous rejection of claims 1-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Malecha et al in view of Okuno et al and Nagamine et al is withdrawn because Okuno et al did not teach a sexually reproductive neomale *A. vulgare*.

Applicant's arguments are moot as the rejection has been withdrawn.

Conclusion

No claim is allowed. Claims 6-9 appear to be free of the prior art of record because the prior art of record does not teach or suggest a method of producing a population of shrimp or prawns having a skewed percentage of females to males comprising: breeding a neomale shrimp or

prawn which does not contain transplanted androgenic tissue with a corresponding female shrimp or prawn, wher by a population of shrimp or prawns having a skewed percentage of females to males is produced.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Patsy Zimmerman whose telephone number is (703) 308-0009.

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Art Unit 1632

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